TECHNICAL BULLETIN

OCCUPATIONAL AND ENVIRONMENTAL HEALTH

CONTROL OF HAZARDS TO HEALTH FROM IONIZING RADIATION USED BY THE ARMY MEDICAL DEPARTMENT

HEADQUARTERS, DEPARTMENT OF THE ARMY

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DEPARTMENT OF THE ARMY
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Chapter 1
Introduction

1–1. Purpose

This technical bulletin—

a. Prescribes general requirements and delineates responsibilities for the use and control of ionizing radiation within the U.S. Army Medical Department (AMEDD).

b. Applies to the Active Army, U.S. Army Reserve, and National Guard Bureau within the continental United States and outside the continental United States (OCONUS) using ionizing radiation for medical purposes.

c. Outlines procedures for obtaining, renewing, and amending U.S. Nuclear Regulatory Commission (NRC) licenses and Department of the Army Radiation Authorization (DARA).

d. Supplements and complements NRC, Department of Transportation, Department of Labor, and Food and Drug Administration (FDA) requirements pertaining to the use, control, transport, and safeguard of ionizing radiation.

1–2. References

Required and related publications and prescribed and referenced forms are listed in appendix A.

1–3. Explanation of abbreviations and terms

Abbreviations and special terms used in this TB MED are explained in the glossary.

1–4. Responsibilities

a. The Surgeon General (TSG) will perform the responsibilities delineated in AR 10–5. In addition, TSG will—

(1) Approve all radiation protection officers (RPOs) at medical organizations authorized to use radioactive materials other than those authorized by registration certificates.

(2) Issue, review, and amend medical DARAs to qualified applicants.

(3) Issue, review, and amend DA radioactive material permits for the medical use of radioactive material on Army installations by non-Army organizations.

(4) Act as liaison with NRC for Army medical licensing.

(5) Approve the use of investigational radiopharmaceuticals according to AR 40–7.

(6) Approve the use of radioactive materials in clinical investigations according to AR 40–38.

(7) Approve the use of the human volunteers when the studies come within the guidelines of this TB MED and AR 70–25.

(8) Designate a Radiation Control Committee to assess the use of radioactive materials by evaluating the documentation submitted by Army medical organizations according to this TB MED and other directives.

b. The Commander, U.S. Army Health Services Command (HSC) will perform the responsibilities delineated in AR 10–43. In addition, the Commander, HSC will—

(1) Ensure that all organizations under the jurisdiction of HSC comply with the requirements of this TB MED and applicable Federal directives.

(2) Evaluate each HSC organization licensed to use radioactive material at least every 2 years.

(3) Review for technical accuracy all DA permits, NRC licenses, and DARA applications for use of radioactive materials at HSC organizations.

(4) Act as liaison with the NRC for Army medical licensing when authority has been delegated by TSG.

c. The Commander, U.S. Army Medical Research and Development Command (MRDC) will ensure that organizations under MRDC jurisdiction—

(1) Possess proper authorization, including a valid NRC license or DARA, prior to procuring or using radioactive materials or ionizing radiation.

(2) Possess proper authorization to use investigational radiopharmaceuticals (AR 40–7).

(3) Acquire written approval from the Secretary of the Army (AR 70–25) prior to submitting a DA permit, NRC license, or DARA application for use in humans (when human volunteers are to be used as experimental research subjects).

(4) Possess adequate resources and procedures for the safe handling and control of radioactive materials and other sources of ionizing radiation.

d. Commanders of oversea medical commands will comply with the requirements of this TB MED and the requirements of the host country as applicable. (In oversea workplaces where the applicable Status of Force Agreements specifically require that U.S. Forces standards comply with host country law, host country standards take precedence if stricter. If host country law is less strict or nonexistent, Army requirements will apply.) In addition, they will—

(1) Ensure that all medical organizations under the command's jurisdiction comply with the provisions of this TB MED.

(2) Evaluate each medical organization processing a DARA at least every 2 years for compliance with this TB MED.

(3) Review for technical accuracy all DA permits and DARA applications for use of radioactive materials at medical organizations under the command's jurisdiction.

e. The commanders of each medical organization will—

(1) Control all aspects of the Radiation Protection Program within their command.

(2) Ensure that their organization possesses a valid NRC license or DARA for the use of radioactive materials. An application for NRC license or DARA for radioactive materials to be used in diagnosis or therapy will not be processed unless the organization has been designated by TSG, HSC, or an OCONUS medical command commander to provide nuclear medicine or radiation therapy services.

(15) Evaluate hazard potential and adequacy of protective measures for existing and proposed operations.

(16) Monitor situations where higher than normal levels of radiation or radioactive contaminants are suspected.

(17) Investigate radiation accidents and incidents and overexposures to determine the cause and take steps to prevent recurrence.

(18) Terminate a program or procedure involving the use of radioactive material or radiation producing devices which are determined to be a medical threat to health and property.

(19) Keep all licenses and DARAs up to date and initiate amendments and requests for renewals when appropriate.

(20) Maintain a current registry of ionizing radiation producing devices, such as x-ray machines, per TB MED 521.

h. The user(s) of radioactive materials in or on humans for diagnostic, therapeutic, or investigational purposes will be a physician approved by the organization's commander only after recommendation by the Radiation Control Committee.

(1) *Approved physician users may delegate the following authorities only to another physician under their direct supervision* within the constraints delineated by appropriate NRC rules, regulatory guides, and local command policy:

(a) The approval of procedures involving the administration of radiopharmaceuticals to patients or the application of ionizing radiation to patients for therapy.

(b) The prescription of the radiopharmaceutical or source of ionizing radiation and the amount of dose to be administered.

(c) The determination of the route of administration.

(d) The interpretation of the results from diagnostic procedures in which radiopharmaceutials are administered.

(2) *The approved physician user(s) may authorize qualified paramedical personnel* to—

(a) Prepare and quality control test radiopharmaceuticals and sources of ionizing radiation.

(b) Measure radiopharamceutical doses prior to patient administration.

(c) Use appropriate instrumentation for the collection of data to be used by the physician.

(d) Administer radiopharmaceuticals and radiation to patients if permitted by applicable Federal directives. Paramedical personnel will *not* administer a therapeutic dose of radiation or radioactive material to a patient unless a physician user or a physician under the direct supervision of a physician user is in attendance. This provision applies only to radioactivity levels which require hospitalization.

(3) *The approved physician user(s) may delegate the following authorities to credentialed nuclear pharmacists* (approved by the local Radiation Control Committee) under their direct supervision. The delegated pharmacist may—

(a) Prescribe radiopharmaceuticals and the amount or dose to be administered.

(b) Determine route of administration.

(c) Prepare the radiopharmaceuticals.

(d) Maintain quality assurance of the radiopharmaceuticals.

(e) Measure the radiopharmaceutical activity prior to patient administration.

(f) Ensure the quality assurance of appropriate instrumentation used within the nuclear pharmacy.

(g) Administer radiopharmaceuticals to patients as delineated by local command policy.

i. The chief of pharmacy or the chief, nuclear medicine service, will—

(1) Ensure that nuclear pharmacists receive appropriate training to maintain proficiency in the field of nuclear pharmacy and any additional training when new duties are added.

(2) Maintain records of such training.

Chapter 2
Requirements

For nonroutine use of radioactive materials, clinical studies, and DA Form completion, see appendixes B, C, and D.

Section I
General Requirements

2–1. Exposure level

Ionizing radiation exposure will be kept ALARA.

2–2. Dosimetry

Personnel dosimetry will be used according to AR 40–14.

2–3. Night vision adaptometers

Night vision adaptometers will be procured, handled, leak tested, controlled, and disposed of as specified in AR 40–61 and SB 8–74.

2–4. X-ray systems

Diagnostic x-ray, therapeutic x-ray, and gamma-beam systems will be used and controlled according to the requirements outlined in TB MED 521.

2–5. Personnel

a. The AMEDD elements using ionizing radiation for therapy or radioactive materials for human use will have a qualified, full-time RPO approved by TSG.

b. Training, qualifications, and experience of medical and paramedical personnel working with radiation sources will comply with the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) Accreditation Manual for Hospitals standards, NRC guides, and Federal regulations.

2–6. Additional requirements

a. Licensed activities will be conducted according to the requirements of 10 CFR and guidance obtained from NRC regulatory guides except where further restricted by applicable law or agreement.

b. The procurement, generation, ownership, possession, application, and disposal of any radioactive materials for medical use will be only as authorized by an existing NRC license or DARA, as applicable.

c. Radioactive materials will be shipped and transported according to the requirements of 49 CFR except where further restricted by applicable law or agreement.

d. Calibration of radiation sources will be according to Army, NRC, or JCAHO requirements as appropriate.

e. Eye protection will be provided as described in AR 40–5, AR 40–14, and TB MED 506.

2–7. Medical surveillance

Medical surveillance will be performed as described in AR 40–14.

2–8. The Radiation Control Committee

For those activities possessing NRC licenses under 10 CFR 35, minimum committee membership will include the deputy commander for clinical services (chairman); chief, nuclear medicine clinic; nuclear pharmacist when assigned; chief, radiation therapy clinic; medical physicist when assigned; the RPO; chief, department of radiology; a representative from the department of nursing; a representative from any department/area in the medical activity wherein radioactive material is used; and chief, biomedical equipment maintenance. A representative from the dental activity is optional.

2–9. Training for nuclear pharmacists

a. Nuclear pharmacists will receive appropriate training to maintain proficiency in the field of nuclear pharmacy.

b. Entry level training and experience in the practice of nuclear pharmacy will include, but are not limited to, the following professional and administrative areas:

(1) Nuclear pharmacy administration.

(2) Radiopharmaceutical distribution and inventory control.

(3) Technology and quality control.

(4) Radiotracer development and evaluation.

(5) Radiopharmaceutical chemistry and tracer methodology.

(6) Radiological health activities.

(7) Clinical services.

Section II
Reporting Requirements

2–10. Radiation Control Committee Report (RCS MED–197)

This report will—

a. Provide TSG; the Commanding General, HSC; and commanders, oversea medical commands with an overview of the effectiveness of radiation protection programs in organizations using radioactive materials for diagnostic, therapeutic, or research applications. Review of this report will constitute a review of the ALARA program and will assist in identifying trends and common areas of difficulty so that corrective action can be initiated as appropriate.

b. As a minimum, include the minutes of all Radiation Control Committee meetings held during the reporting period. The minutes will address radiation worker training, quarterly ALARA program summaries, radiation incident events and actions, identification of problem areas, and other areas as determined by the chairman.

Appendix A
References

Section I
Required Publications

AR 10–5
Department of the Army. (Cited in para 1–4*a*.)

AR 10–43
U.S. Army Health Services Command. (Cited in para 1–4*b*.)

AR 25–400–2
The Modern Army Recordkeeping System (MARKS). (Cited in para D–1.)

AR 40–5
Preventive Medicine. (Cited in paras 1–1*e* and 2–6*e*.)

AR 40–7
Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances. (Cited in paras 1–4*a*(5), 1–4*c*(2), and B–3.)

AR 40–14
Control and Recording Procedures for Exposure to Ionizing Radiation and Radioactive Materials. (Cited in paras 2–2, 2–6*e*, 2–7, 2–12*b*, and B–2*k*(7).)

AR 40–38
Clinical Investigation Program. (Cited in paras 1–4*a*(6), B–2, B–2*i*, and B–3.)

AR 40–61
Medical Logistics Policies and Procedures. (Cited in paras 2–3 and D–1*b*.)

AR 70–25
Use of Volunteers as Subjects of Research. (Cited in paras 1–4*a*(7), 1–4*c*(3), and B–3.)

AR 385–11
Ionizing Radiation Protection (Licensing, Control, Transportation, Disposal, and Radiation Safety). (Cited in para D–2.)

AR 385–40
Accident Reporting and Records (Cited in para 2–12*a*.)

JCAHO Manual
Joint Commission on Accreditation of Healthcare Organizations Accreditation for Hospitals Manual. (Cited in para 2–5*b*.) (The current edition of this publication may be obtained from JCAHO, 875 N. Michigan Ave., Chicago, IL 60611.)

NCRP Reports
Reports of the National Council on Radiation Protection and Measurements. (Cited in para 2–16*d*.) (These reports are issued on a standing order basis from NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.)

NRC Licensing Guide No. 10.8
NRC Licensing Guide for Preparation of Applications for Medical Programs. (Cited in para 2–16*a*.) (This publication may be obtained from NRC, ATTN: Distribution Section, Washington, DC 20555.)

NRC Regulatory Guide No. 7.3
Procedures for Picking Up and Receiving Packages of Radioactive Material. (Cited in paras 2–16*a* and D–2.) (To obtain this publication, see NRC Licensing Guide No. 10.8 entry above.)

NRC Regulatory Guide No. 7.4
Leakage Tests on Packages for Shipment of Radioactive Materials. (Cited in paras 2–16*a* and D–2.) (To obtain this publication, see NRC Licensing Guide No. 10.8 entry above.)

NRC Regulatory Guide No. 8.13
Instruction Concerning Prenatal Radiation Exposure. (Cited in para 2–16*a*.) (To obtain this publication, see NRC Licensing Guide No. 10.8 entry above.)

NRC Regulatory Guide No. 8.18
Information Relevant to Insuring that Occupational Radiation Exposures at Medical Institutions Will Be as Low as Reasonably Achievable. (Cited in para 2–16*a*.) (To obtain this publication, see NRC Licensing Guide No. 10.8 entry above.)

NRC Regulatory Guide No. 8.23
Radiation Safety Surveys at Medical Institutions. (Cited in paras 1–4*g*(14) and 2–16*a*.) (To obtain this publication, see NRC Licensing Guide No. 10.8 entry above.)

NRC Regulatory Guide No. 8.29
Instructions Concerning Risks from Occupational Radiation Exposure. (Cited in para 2–16*a*.) (To obtain this publication, see NRC Licensing Guide No. 10.8 entry above.)

SB 8–74
Adaptometer, Radioactive Plaque, Night Vision (NSN 6515–00–382–1000), AEC License No. 37–11831–01. (Cited in para 2–3.)

TB MED 506
Occupational Vision. (Cited in para 2–6*e*.)

TB MED 521
Management and Control of Diagnostic X-Ray, Therapeutic X-Ray, and Gamma-Beam Equipment. (Cited in paras 1–4*g*(20) and 2–4.)

10 CFR
Energy.
(Cited in paras 1–4*f*(3), 1–4*g*, 2–6*a*, 2–8, 2–11*a*, 2–13*d*(1), B–1, C–1, D–2, and the glossary.) (This publication may be obtained on a subscription basis from the Superintendent of Documents, Government Printing Office, Washington, DC 20402.)

Appendix B
Nonroutine Human Use of Radioactive Materials

B–1. Experimental and nonroutine human use of radioactive materials include all those uses not specified in 10 CFR 35.100.

a. Radiopharmaceuticals for diagnostic or therapeutic purposes for which a *Notice of Claimed Investigational Exemption for a New Drug* has been accepted by the FDA according to 21 CFR 310 will be used according to the manufacturer's instructions. The protocol will be approved prior to use as specified in paragraph B–2.

b. Nonroutine human use will be classified into one of two phases of development—

(1) *Clinical research.*

(a) Clinical research applies to a new use of radioactive material in humans. Little or nothing is known about the procedure and little or nothing has been published on the subject. The basis for proceeding with the new use in humans is derived from knowledge obtained from animal studies. This phase of development includes the initial introduction into humans and initial trials on a limited number of patients.

(b) The clinical research phase of experimental or nonroutine medical use of radioactive material is normally limited to licensees who—

1 Have personnel with broad experience in the clinical use of radioactive material, and

2 Have appropriate facilities and equipment available to conduct research.

(c) Research should be pursued by groups of competent investigators representing different disciplines rather than by single individuals. The individual physician will not be designated on the license as the authorized user, but should normally have broad and varied experience in the use of radioactive materials and in clinical research investigation.

(2) *Clinical evaluation.*

(a) Clinical evaluation applies to the planned testing of a new diagnostic or therapeutic procedure in an appropriate series of controlled and diseased humans. The procedure and results of clinical research will ordinarily have been reported in the literature or at meetings. If adequate information has not been published, the applicant should have spent sufficient time with those who developed the test to be thoroughly familiar with the details.

(b) The clinical evaluation phase of experimental or nonroutine medical use of radioactive material is normally limited to licensees under the supervision of an individual physician with broad experience in clinical evaluation and the use of radioactive materials, and under the guidance of a Radiation Control Committee representing a number of disciplines.

B–2. Applications for experimental or nonroutine uses of radioactive materials in humans will be reviewed by the Radiation Control, the Clinical Investigation, and the Human Use Committees (AR 40–38) before submitting applications through command channels to TSG (HQDA (DASG–PSP–E), 5109 Leesburg Pike, Falls Church, VA 22041–3258). Applications will be supported by a research protocol which includes—

a. The title of the study.

b. The purpose for conducting the study. Indicate whether the study is to be clinical research or clinical evaluation and explain why.

c. The plan of investigation in sufficient detail to permit a critical evaluation of the methods for conducting the experiments and the controls established.

d. A statement as to whether any planned complementary drug or radiopharmaceutical administration is contemplated along with the study.

e. A statement about the expected fate of the radioisotope administered and, if the procedure is for therapy, a statement about the expected effects.

f. An outline of related work conducted by the applicant or others in laboratory animals and in humans, *if the application is for clinical research.* Include data on localization, effective half-life, radiation dosage, and dosage to the critical organ and whole-body. If no work has been conducted in animals, explain why. Pertinent references and a brief abstract prepared by the applicant of published or unpublished material should be submitted. (The brochure of a commercial supplier is not a satisfactory authority for this purpose. It is not necessary to include reprints of references with the application.)

g. Pertinent references and a brief abstract prepared by the applicant of published or unpublished material, *if the application is for clinical evaluation.* Include information on localization, effective half-life, and radiation dosage. (The brochure of a commercial supplier is not a satisfactory authority for this purpose. It is not necessary to include reprints of references with the application.)

h. A description of the human subjects to be studied:

(1) Persons without manifest disease—number, method of selection, and age range.

(2) Persons with manifest disease—number, nature of pathology, method of selection, and age range.

(3) Pregnant women—ordinarily excluded from any test not involving the condition of pregnancy itself. Specify whether or not pregnant women will be tested, and if so, explain why.

(4) Minors—ordinarily excluded. Specify whether or not minors will be tested, and if so, explain why.

i. Confirmation that consent of human subjects, or their representatives, will be obtained to participate in the investigation except where this is not feasible or, in the investigator's professional judgment, is contrary to the best interests of the subjects (AR 40–38).

Appendix C
List of Well Established Procedures Currently Authorized for Clinical Studies

C–1. The list of well established procedures currently authorized for clinical studies includes all of those listed in 10 CFR.

C–2. The additional procedures, in groups I through IV of table C–1 are also well established and currently authorized. The procedures use either naturally occurring or accelerator produced radioactive materials for which the NRC does not have statutory responsibility. Collectively such radioactive materials are called NARM (naturally occurring and accelerator produced radioactive material).

Table C–1.
NARM procedures

Group I. Diagnostic studies involving measurements of uptake, dilution, and excretion

Radionuclide	Chemical form	Use	Recommended dosage range
Iodine-123	Sodium iodide	Thyroid uptake	Up to 100 microcuries
Cobalt-57	Labeled cyanocobalamine	Intestinal absorption studies	Up to 0.5 microcuries
Sodium-22	Chloride	Sodium space determinations	Up to 40 microcuries

Group II. Diagnostic study involving imaging and tumor localization

Radionuclide	Chemical form	Use	Recommended dosage range
Iodine-123	Sodium iodide	Thyroid imaging	Up to 2 millicuries
Gallium-67	Citrate	Tumor and abscess localization	Up to 5 millicuries

Group III. Special diagnostic uses of radiopharmaceuticals

Radionuclide	Chemical form	Use	Recommended dosage range
Indium-111	DTPA	Cisternography	Up to 2 millicuries
Indium-111	Chloride	Malignant neoplasm and bone marrow imaging	Up to 3 millicuries
Indium-111	Oxine	*In vivo* white cell and platelet studies	Up to 15 millicuries

Group IV. Therapeutic or diagnostic use of sealed beta particle and gamma ray sources

Radionuclide	Chemical form	Use
Radium-226	Sealed source (needles and cells)	Topical, interstitial or intracavitary therapy of cancer
Radon-222	Seeds	Interstitial treatment of cancer

Appendix D
Instructions for Completing DA Forms

D–1. Logs and records

The RPO will maintain a centralized system of records for procurement, receipt, use, transfer, disposal surveys, leak tests, personnel monitoring, inventories, and all other records associated with the use of radioactive materials/radiation sources according to AR 25–400–2.

a. Radiopharmaceutical inventory records. Nuclear medicine service personnel will maintain an inventory of each radiopharmaceutical received, used, lost through radioactive decay, or disposed. In addition, records will be maintained showing the supplier, lot number, date of administration, name of requesting physician, identity and activity of the radiopharmaceutical, and identity of the recipient. DA Form 4574–R (Radiopharmaceutical Stock Record) will be used for this purpose and is authorized for local reproduction on 8½- by 11-inch paper. (DA Form 4574–R is located at the end of this publication.) Medical facilities using large numbers and amounts of radioactive materials having automatic data processing (ADP) capability may use this capability provided required program information is included.

b. Inventory and leak test records. Inventory and leak test records will be maintained on a consecutive entry log and the removable activity will be recorded in microcuries. DA Form 3862 (Controlled Substances Stock Records) may be adapted for this purpose. Medical facilities using large numbers and amounts of radioactive materials and having ADP may use this capability provided all required program information is included (see AR 40–61).

c. Instrument logs. Instrument logs will be maintained indicating calibration and maintenance.

D–2. Shipment and receipt of radioactive material

DA Form 3252–R (Punch Card Transmission Worksheet—Radioisotope Inventory and Leak Test Report) is not required to document the receipt of radiopharmaceuticals provided other suitable records are maintained. However, the preparation of DA Form 3252–R is required for the receipt of other radioactive materials and the shipments thereof as specified in AR 385–11 and TM 55–315. Surveys will be performed as specified in 10 CFR 20.205. See NRC Regulatory Guides 7.3 and 7.4.

a. The pickup of radioactive material will be accomplished as soon as practicable (if possible within 2 or 3 hours) after receiving notification by the carrier that the material is available for pickup.

b. A package arriving at the consignee's facility during normal duty hours will be monitored with an appropriate radiation detection instrument for leakage and radioactive contamination within 3 hours. (Monitoring at the time of receipt is preferred.)

c. Packages arriving during nonduty hours will be monitored within 18 hours of receipt. (Monitoring at the time of receipt is preferred.)

d. The outer and inner surfaces of each package or container will be monitored while it is being opened and before the packaging of the contents is removed from the unpacking location.

e. Each medical organization will—

(1) Establish and maintain written procedures for safely opening packages containing radioactive material.

(2) Ensure that such procedures are followed and that due consideration is given to special instructions for the type of package being opened.

Glossary

Section I
Abbreviations

ADP
automatic data processing

ALARA
as low as is reasonably achievable

AMEDD
U.S. Army Medical Department

CFR
Code of Federal Regulations

DARA
Department of the Army Radiation Authorization

FDA
Food and Drug Administration

HSC
U.S. Army Health Services Command

JCAHO
Joint Commission on the Accreditation of Healthcare Organizations

MEDCEN
U.S. Army medical center

MEDDAC
U.S. Army medical activity

MRDC
(U.S. Army) Medical Research and Development Command

NARM
naturally occurring and accelerator-produced radioactive material

NCRP
National Council on Radiation Protection and Measurements

NRC
U.S. Nuclear Regulatory Commission

OCONUS
outside continental United States

RPO
radiation protection officer

TSG
The Surgeon General

Section II
Terms

DA Radioactive Authorization
Authority issued to a commander of a medical facility by TSG for the medical use of radioactive materials which are *either* not subject to licensing or control by the NRC.

In vitro
Within an artificial environment as in a test tube.

In vivo
Within a living organism.

Licensing
The process of acquiring authority to use radioactive materials or the radiation therefrom for medical use. It includes the process of obtaining both NRC licenses and DARAs.

Installation medical authority
The unit surgeon, command chief surgeon, MEDDAC and/or MEDCEN commander, and the director of health services or his or her representative responsible for provision of medical support at the unit, command, or installation concerned.

Medical use
The application of ionizing radiation or its source for diagnostic, therapeutic, or investigative purposes in support of the healing arts. Medical use may be subdivided into—

a. Human use. Medical use for living persons.

b. Nonhuman use. Medical use in any fashion not fitting the definition of human use. Typically, it includes medical use application on nonhuman organisms, human remains, and *in vitro* procedures.

Misadministration
The administration of—

a. A radiopharmaceutical or radiation from a source other than the one intended.

b. A radiopharmaceutical or radiation to the wrong patient.

c. A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician.

d. A diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent.

e. A therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent.

f. A therapeutic radiation dose from a sealed radioisotope source, an accelerator, an x-ray producing device, or other ionizing radiation producing device such that errors in calibration, time of exposure, and/or treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.

Naturally Occurring and Accelerator-Produced Radioactive Materials

Radionuclides which do not fall within the purview of the NRC, are found in nature (such as radium and radon) or are generated as the result of the operation of an accelerator (such as cobalt-57 and iodine-123).

The proponent agency of this bulletin is the Office of The Surgeon General. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) direct to HQDA (DASG–PSP), 5109 Leesburg Pike, Falls Church, VA 22041–3258.

By Order of the Secretary of the Army:

CARL E. VUONO
General, United States Army
Chief of Staff

Official:

R. L. DILWORTH
Brigadier General, United States Army
The Adjutant General

DISTRIBUTION:
Active Army, ARNG, USAR to be distributed in accordance with DA Form 12–34C–R requirements for TB MED Series: Radiology.

RADIOPHARMACEUTICAL STOCK RECORD

For use of this form, see TB MED 525; the proponent agency is the Office of The Surgeon General

Place Package Label in This Space

RADIOPHARMACEUTICAL	MANUFACTURER	DATE
	LOT NUMBER	EXPIRATION DATE

NUMBER	PATIENT NAME	PROCEDURE	DATE	TIME	ASSAY (mCi/ml)	PATIENT DOSE		BALANCE REMAINING (ml)	PRESCRIPTION NUMBER	ADMINISTERED BY (initials)
						ACTIVITY (mCi)	VOLUME (ml)			

DA FORM 4574-R, 1 NOV 76